

REMARKS:

Reconsideration of the rejections is respectfully requested.

The status of the claims is as follows:

Amended:	1, 8, 13
Cancelled:	None
New:	14-19
Pending:	1, 3-19

The claims have been amended to more clearly define the invention. Support for the amendments is either apparent, or is described in the text below. New claims 14-17 find support, for example, at 14:3-5. New claims 18-19 find support in the paragraph bridging pages 6-7, and the Examples.

Claim Rejections - 35 U.S.C. §112, Second Paragraph

Claims 1-7 and 13 stood rejected under 35 U.S.C. §112, second paragraph, based on an assertion that certain terms in the claim rendered the claims insufficient to particularly point out and distinctly claim the subject matter that the applicant regards as the invention. As to the objection to antecedent for “active ingredient,” the recital has been changed to recite the implied antecedent. On the objection to claim 4 as not further limiting the claims, Applicant respectfully submits that a substance can be pharmaceutically acceptable without having to be approved by U.S. regulatory authority. Accordingly, claim 4 excludes some subject matter of its parent claim.

Claim Rejections - 35 U.S.C. §103(a)

Claims 8-12 stand rejected under 35 U.S.C. §103(a), based on Mitra, US 6,056,975. Applicant respectfully traverses. All of the exemplification of Mitra uses excipients. In introducing the subject matter, the patent recites that the preparations contain at least one

excipient – which implies a material amount. See, 2:66. It may be that some Mitra preparations, which are stabilized based on using select excipients, are relatively stable. However, clearly the present claims recite an altogether different way to solve this art-recognized problem.

Accordingly, Applicant respectfully submits that the rejection is in error.

Applicant respectfully submits that the reconstructions of the invention set forth in the Office Action, for example regarding particle size, are made with improper hindsight. The formulation of claim 8 is without excipients used in the prior art to provide a dissolution profile. Without excipients and in the claimed dosage formulation, Applicant respectfully submits that the Examiner cannot infer what particle size would be appropriate for an appropriate dissolution profile.

Applicant respectfully notes that the language discounted in the Office Action, which is now somewhat modified, recites structure. The drug is deposited on the polymer, not co-mixed with the polymer as would be required to apply the rejection asserted in the Office Action.



DOCKET NO. DEL-062B
SERIAL NO. 09/900,094

Conclusion

In light of the above discussion and amendments, it is respectfully submitted that the claims are in condition for allowance. The issuance of a Notice of Allowance is earnestly solicited.²

Respectfully submitted,

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² **FEE DEFICIENCY**

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